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PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT & TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of
Frieder K. Kempe
Serial No.: 10/682,083 Art Unit: 3771
Filed: 10/10/2003 Examiner: Shumaya B. Ali
For: **METHOD AND ARTICLE FOR TREATMENT OF INFLAMMATORY DISEASE**

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

AMENDED APPEAL BRIEF Pursuant to 37 CFR §41.37

Further to the Notice of Appeal filed May 26, 2008, the Appellant hereby files this brief in accordance with 37 CFR §41.37 in support of an Appeal from the final rejection of the above-noted application. This is an appeal from the Final Rejection mailed November 26, 2007. A Notice of Appeal was filed May 26, 2008 and accordingly the term to file the Appeal Brief expired July 26, 2008. A Petition for a four-month extension of time is filed herewith. The Appeal Brief is filed in triplicate and the accompanying cheque includes the small entity filing fee of $270 and extension fee of $865.

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Real party in interest

The subject application is owned by Frieder K. Kempe.

Related appeals and interferences

There are no related appeals or interferences.

Status of claims

On May 26, 2008 the appellant appealed from the final rejection of claims 1-70. All of the claims 1-70 stand rejected and are under appeal. No claims have been cancelled or withdrawn.

Status of amendments

No amendment has been made subsequent to the Examiner's Final Office Action mailed November 26, 2007.

Summary of claimed subject matter

The independent claims involved in the appeal are claims 1 and 11. The presently claimed invention as claimed in Claim 1 is a method of treatment of pain in a patient caused by an inflammatory disease comprising shielding the affected areas of the patient from high frequency electromagnetic radiation, while not shielding said affected areas from low frequency electromagnetic radiation, for a period of time sufficient to reduce the symptoms. The subject matter of claim 1 is described at p. 5, line 9 through page 6 line 28 of the disclosure.

Claim 11 is directed to a method of treatment of pain in a patient caused by an inflammatory disease comprising the steps of: (i) providing an article of clothing configured to substantially cover the affected areas of the patient with a high-frequency electromagnetic radiation shielding cloth which does not shield low frequency electromagnetic radiation; and (ii) said patient wearing said article of clothing whereby said affected areas of said patient are substantially covered by said cloth over a period of time sufficient to reduce said pain. The subject matter of claim 11 is described at p. 5, line 9 through page 6 line 28 of the disclosure.

There are no means plus function or step plus function limitations in the independent claims 1 and 11.

Grounds of rejection to be reviewed on appeal

The following grounds of rejection in the Office Action mailed 11/26/2007 are to be reviewed:

In the Office Action mailed 11/26/2007, the Examiner rejected claims 1-70 under 35 U.S.C. 103(a) as unpatentable over Kempe US Patent No. 6,146,351. This is the sole ground of rejection and the sole ground of rejection to be reviewed.

Argument

In the Office Action mailed 11/26/2007, the Examiner rejected claims 1-70 under 35 U.S.C. 103(a) as unpatentable over Kempe US Patent No. 6,146,351. The Examiner states that it would have been obvious to one of ordinary skill in the art to consider Kempe's article can be used for treating pain caused by inflammatory disease because since if that article was worn by a person having an inflammatory disease in addition to DOMS, then while receiving a treatment for the DOMS, that person would inherently receive a treatment for pain caused by the inflammatory disease.

The Examiner in particular rejects independent method claims 1 and 11 on the basis that (page 2, last line through page 3 line 4), "it would have been obvious to one of ordinary skill in the art to consider Kempe's article can be used for treating pain caused by inflammatory disease because if that article was worn by a person having an inflammatory disease in addition to DOMS, then while receiving a treatment for the DOMS, that person would inherently receive a treatment for pain caused by the inflammatory disease." While at page 5, 7th last line, the Examiner agrees that DOMS is different from pain caused by inflammatory disease, the Examiner continues, "[I]n the claimed invention the pain cause [*sic*] by inflammatory disease is being treated with a garment made from FARABLOC. Thus a person with DOMS and pain from inflammatory disease getting treated for DOMS using Kempe's apparatus would inherently receive a treatment for his pain caused by inflammatory disease. Thus, it would have been obvious to one of ordinary skill in the art to carry out claimed method steps using the apparatus of Kempe."

I) Rejection of claims 1 and 11 under 35 U.S.C. s. 103(a)

Firstly, the Examiner has not satisfied the requirements stated in the MPEP for a rejection based on inherency As stated in the MPEP paragraph 2112,

> The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "**To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.**' " (emphasis added) *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) (The claims were drawn to a disposable diaper having three fastening elements. The reference disclosed two fastening elements that could perform the same function as the three fastening elements in the claims. The court construed the claims to require three separate elements and held that the reference did not disclose a separate third fastening element, either expressly or inherently.). >Also, "[a]n invitation to investigate is not an inherent disclosure" where a prior art reference "discloses no more than a broad genus of potential applications of its discoveries." *Metabolite Labs., Inc. v. Lab. Corp. of*

Am. Holdings, 370 F.3d 1354, 1367, 71 USPQ2d 1081, 1091 (Fed. Cir. 2004) (explaining that "[a] prior art reference that discloses a genus still does not inherently disclose all species within that broad category" but must be examined to see if a disclosure of the claimed species has been made or whether the prior art reference merely invites further experimentation to find the species.<

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy,* 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) (Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients). The examiner applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (blow molding). The reference did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis in original). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board reversed on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.).

Kempe United States Patent no. 6,146,351 cited by the Examiner discloses a method of reducing delayed onset muscle soreness, which is a pain resulting from unaccustomed exercise. The method involves covering the affected portion of the body with a radiation-shielding textile. A suitable radiation-shielding textile is that sold under the trademark FARABLOC . In the present case, the Examiner relies on the contention that if the FARABLOC article was worn by a person having an inflammatory disease in addition to DOMS, then while receiving a treatment for the DOMS, that person would inherently receive a treatment for the inflammatory disease. However there is no basis in fact or evidence that a person receiving treatment for DOMS must necessarily have an inflammatory disease. As evidenced in the declarations of Dr. Douglas B. Clement and Dr. Cecil Hershler, it is incorrect to characterize Delayed Onset Muscle Soreness (DOMS) as an inflammatory disease. This is acknowledged by the Examiner. DOMS is a direct result of injury to muscle from micro-trauma secondary to overuse (i.e. unaccustomed exercise). By contrast, an inflammatory disease is created by an autoimmune disorder or infective agent, not micro-trauma. Thus there is no evidence of any connection between DOMS and an inflammatory disease. A person suffering from DOMS would not necessarily also suffer from an inflammatory disease. Further, for the person receiving a treatment for DOMS to also inherently receive a treatment for the inflammatory disease as claimed, it would be necessary that the DOMS-affected area be the same area of the body as that affected by the inflammatory disease. Not only is it purely speculative and without foundation in evidence that such would necessarily occur, it is also counter-intuitive that such would occur since an individual having an inflammatory disease in a part of that person's body would not likely subject that part to unaccustomed exercise. There is thus no logical connection between a person treating a body part for DOMS and also having an inflammatory disease affecting that part. Hence the requirements for a rejection based on inherency have not been met. The currently claimed method was not a necessary feature of the Kempe '351 method.

The Examiner's rejection is based on obviousness rather than inherent anticipation. The inherent teaching of a prior art reference is a question of fact which arises both in the context of anticipation and obviousness. *In re Napier,* 55 F. 3d 610, 613, 34 USPQ 2d 1782, 1784 (Fed. Cir. 1995); *In re Grasselli*, 713 F. 2d 731, 739, 218 USPQ 769, 775 (Fed Cir. 1983). However as noted above, Kempe '351 does not inherently teach treatment for the inflammatory disease as claimed since the currently claimed method is not necessarily present in the Kempe '351 method. An obviousness-based rejection based on inherency is similarly not applicable in the present case. For the method claims 1 and 11 herein to be rendered obvious by Kempe US Patent No. 6,146,351, it must have been obvious to the person skilled in the art that if the FARABLOC article was worn for treatment of DOMS in a particular body part by a person having an inflammatory disease of that body part, that the treatment would also be effective for the inflammatory disease. Yet the evidence of those skilled in the art as evidenced by the declarations of Dr. Douglas B. Clement and Dr. Cecil Hershler is that it would not be obvious that a treatment which reduces Delayed Onset Muscle Soreness (DOMS) would also successfully treat inflammatory diseases. There is no basis in the record, evidentiary or otherwise, that contradicts the evidence of Dr. Douglas B. Clement and Dr. Cecil Hershler.

ii) Rejection of claims 2-10 and 12-70 under 35 U.S.C. s. 103(a)

Independent claims 1 and 11 being patentable over the cited art, it is submitted that the dependent claims 2-10 and 12-70 which depend from them are similarly patentable.

Summary

The appellant submits for the foregoing reasons that the Examiner's rejections of independent claims 1 and 11 and dependent claims 2-10, and 12-70 were erroneous and reversal of such rejection is respectfully requested.

Respectfully submitted,

By: ____________________
Bruce M. Green
Registration No.: 30,524

Claims Appendix

Claim 1: A method of treatment of pain in a patient caused by an inflammatory disease comprising shielding the affected areas of the patient from high frequency electromagnetic radiation, while not shielding said affected areas from low frequency electromagnetic radiation, for a period of time sufficient to reduce the symptoms.

Claim 2: The method of claim 1 wherein said high frequency electromagnetic radiation has a frequency greater than 1 megahertz.

Claim 3: The method of claim 2 wherein said low frequency electromagnetic radiation has a frequency less than ~~about~~ 1 megahertz.

Claim 4: The method of claim 1 wherein said shielding is accomplished by covering the affected area of said patient with a radiation-shielding textile for a period of time sufficient to reduce said symptoms.

Claim 5: The method of claim 4 wherein said radiation-shielding textile comprises between two and thirty-five percent by weight of a continuous system of electrically conductive fibers and the remainder of non-conductive fibers.

Claim 6: The method of claim 5 wherein said radiation-shielding textile is a woven cloth and said electrically conductive fibers are stainless steel fibers.

Claim 7: The method of claim 5 wherein said radiation-shielding textile is a woven cloth and said electrically conductive fibers are formed of a material selected from the group copper, silver or ceramic.

Claim 8: The method of claim 5 wherein said radiation-shielding textile is a knitted fabric and said electrically conductive fibers are stainless steel fibers.

Claim 9: The method of claim 5 wherein said radiation-shielding textile is a knitted fabric and said electrically conductive fibers are formed of a material selected from the group copper, silver or ceramic.

Claim 10: The method of claim 8 wherein said radiation-shielding textile comprises about thirteen percent by weight of a continuous system of electrically conductive fibers and the remainder of non-conductive fibers.

Claim 11: A method of treatment of pain in a patient caused by an inflammatory disease comprising the steps of:

(I) providing an article of clothing configured to substantially cover the affected areas of the patient with a high-frequency electromagnetic radiation shielding cloth which does not shield low frequency electromagnetic radiation; and
(ii) said patient wearing said article of clothing whereby said affected areas of said patient are substantially covered by said cloth over a period of time sufficient to reduce said pain.

Claim 12: The method of claim 11 wherein radiation-shielding cloth comprises between two and thirty-five percent by weight of a continuous system of electrically conductive fibers and the remainder of non-conductive fibers.

Claim 13: The method of claim 12 wherein said electrically conductive fibers are formed of a material selected from the group copper, silver or ceramic.

Claim 14: The method of claim 11 wherein said radiation-shielding textile comprises about thirteen percent by weight of a continuous system of electrically conductive fibers and the remainder of non-conductive fibers.

Claim 15: The method of claim 1 wherein said inflammatory disease is selected from the group Achilles tendinitis, Adhesive capsulitis, Ankylosing spondylitis, Anserine bursitis, Avascular necrosis, Bicipital tendinitis, Bursitis, Calcaneal bursitis, Calcium pyrophosphate dihydrate (CPPD), crystal deposition disease, Carpal tunnel syndrome, Chondrocalcinosis, Chondromalacia patellae, Costosternal syndrome, Degenerative joint disease, Dupuytren's contracture, Epicondylitis, Exercise-induced compartment syndrome, Fibromyalgia, Freiberg's disease, Gout, Hypertrophic osteoarthropathy, Impingement syndrome, Myofascial pain syndrome, Neuropathic arthropathy, Olecranon bursitis, Osgood-Schlatter's disease, Osteoarthritis, Osteochondromatosis, Osteoporosis, Paget's disease of bone, Patellofemoral pain syndrome, Plantar fasciitis, Polyarteritis nodosa, Polymyositis, Popliteal cysts, Posterior tibial tendinitis, Prepatellar bursitis, Psoriatic arthritis, Raynaud's phenomenon, Reflex sympathetic dystrophy syndrome, Retrocalcaneal bursitis, Rheumatoid arthritis, Rotator cuff tendinitis, Sacroiliitis, Scheuermann's osteochondritis, Scleroderma, Seronegative arthritis, Shoulder-hand syndrome, Spinal stenosis, Spondylolysis, Systemic lupus erythematosus (SLE), Tarsal tunnel syndrome, Tennis elbow, Traumatic arthritis and Trochanteric bursitis.

Claim 16: The method of claim 1 wherein said inflammatory disease is Achilles tendinitis.

Claim 17: The method of claim 1 wherein said inflammatory disease is Adhesive capsulitis.

Claim 18: The method of claim 1 wherein said inflammatory disease is

Ankylosing spondylitis.

Claim 19: The method of claim 1 wherein said inflammatory disease is Anserine bursitis.

Claim 20: The method of claim 1 wherein said inflammatory disease is Avascular necrosis.

Claim 21: The method of claim 1 wherein said inflammatory disease is Bicipital tendinitis.

Claim 22: The method of claim 1 wherein said inflammatory disease is Bursitis.

Claim 23: The method of claim 1 wherein said inflammatory disease is Calcaneal bursitis.

Claim 24: The method of claim 1 wherein said inflammatory disease is Calcium pyrophosphate dihydrate (CPPD).

Claim 25: The method of claim 1 wherein said inflammatory disease is crystal deposition disease.

Claim 26: The method of claim 1 wherein said inflammatory disease is Carpal tunnel syndrome.

Claim 27: The method of claim 1 wherein said inflammatory disease is Chondrocalcinosis.

Claim 28: The method of claim 1 wherein said inflammatory disease is Chondromalacia patellae.

Claim 29: The method of claim 1 wherein said inflammatory disease is Costosternal syndrome.

Claim 30: The method of claim 1 wherein said inflammatory disease is Degenerative joint disease.

Claim 31: The method of claim 1 wherein said inflammatory disease is Dupuytren's contracture, Epicondylitis.

Claim 32: The method of claim 1 wherein said inflammatory disease is Exercise-induced compartment syndrome.

Claim 33: The method of claim 1 wherein said inflammatory disease is

Fibromyalgia.

Claim 34: The method of claim 1 wherein said inflammatory disease is Freiberg's disease.

Claim 35: The method of claim 1 wherein said inflammatory disease is Gout.

Claim 36: The method of claim 1 wherein said inflammatory disease is Hypertrophic osteoarthropathy.

Claim 37: The method of claim 1 wherein said inflammatory disease is Impingement syndrome.

Claim 38: The method of claim 1 wherein said inflammatory disease is Myofascial pain syndrome.

Claim 39: The method of claim 1 wherein said inflammatory disease is Neuropathic arthropathy.

Claim 40: The method of claim 1 wherein said inflammatory disease is Olecranon bursitis.

Claim 41: The method of claim 1 wherein said inflammatory disease is Osgood-Schlatter's disease.

Claim 42: The method of claim 1 wherein said inflammatory disease is Osteoarthritis.

Claim 43: The method of claim 1 wherein said inflammatory disease is Osteochondromatosis.

Claim 44: The method of claim 1 wherein said inflammatory disease is Osteoporosis.

Claim 45: The method of claim 1 wherein said inflammatory disease is Paget's disease of bone.

Claim 46: The method of claim 1 wherein said inflammatory disease is Patellofemoral pain syndrome.

Claim 47: The method of claim 1 wherein said inflammatory disease is Plantar fasciitis.

Claim 48: The method of claim 1 wherein said inflammatory disease is

Polyarteritis nodosa.

Claim 49: The method of claim 1 wherein said inflammatory disease is Polymyositis.

Claim 50: The method of claim 1 wherein said inflammatory disease is Popliteal cysts.

Claim 51: The method of claim 1 wherein said inflammatory disease is Posterior tibial tendinitis.

Claim 52: The method of claim 1 wherein said inflammatory disease is Prepatellar bursitis.

Claim 53: The method of claim 1 wherein said inflammatory disease is Psoriatic arthritis.

Claim 54: The method of claim 1 wherein said inflammatory disease is Raynaud's phenomenon.

Claim 55: The method of claim 1 wherein said inflammatory disease is Reflex sympathetic dystrophy syndrome.

Claim 56: The method of claim 1 wherein said inflammatory disease is Retrocalcaneal bursitis.

Claim 57: The method of claim 1 wherein said inflammatory disease is Rheumatoid arthritis.

Claim 58: The method of claim 1 wherein said inflammatory disease is Rotator cuff tendinitis.

Claim 59: The method of claim 1 wherein said inflammatory disease is Sacroiliitis.

Claim 60: The method of claim 1 wherein said inflammatory disease is Scheuermann's osteochondritis.

Claim 61: The method of claim 1 wherein said inflammatory disease is Scleroderma.

Claim 62: The method of claim 1 wherein said inflammatory disease is Seronegative arthritis.

Claim 63: The method of claim 1 wherein said inflammatory disease is Shoulder-hand syndrome.

Claim 64: The method of claim 1 wherein said inflammatory disease is Spinal stenosis.

Claim 65: The method of claim 1 wherein said inflammatory disease is Spondylolysis.

Claim 66: The method of claim 1 wherein said inflammatory disease is Systemic lupus erythematosus (SLE).

Claim 67: The method of claim 1 wherein said inflammatory disease is Tarsal tunnel syndrome.

Claim 68: The method of claim 1 wherein said inflammatory disease is Tennis elbow.

Claim 69: The method of claim 1 wherein said inflammatory disease is Traumatic arthritis.

Claim 70: The method of claim 1 wherein said inflammatory disease is Trochanteric bursitis.

Evidence Appendix

Declarations of a) Dr. Douglas B. Clement and b) Dr. Cecil Hershler filed 2/22/07 and entered in the Office Action mailed 03/07/2007 are relied upon in the Appeal.

Paper No.:___

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Inventor(s): Frieder K. Kempe
Title: **METHOD AND ARTICLE FOR THE TREATMENT OF INFLAMMATORY DISEASE**
Serial No.: 10/682,083
Filed: 10/10/2003
Examiner: Shumaya B. Ali Art Unit: 3743
Date: 30 January, 2007

To: Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia
22313-1450

DECLARATION UNDER 37 CFR 1.132

I, Dr. Douglas B. Clement, of #2204 - 1077 West Cordova Street, Vancouver, British Columbia, Canada V6C 2C6, declare as follows:

1. I am a Medical Doctor and Professor Emeritus, Division of Sports Medicine in the Faculty of Medicine of the University of British Columbia. My resume is attached. I have practised in the area of sports medicine for over 45 years. I am a specialist in the field of sports medicine and have authored or co-authored more than 35 published papers in that field.

2. I understand that the United States Patent Office Examiner in this application takes the position that Delayed Onset Muscle Soreness (DOMS) is an inflammatory disease, and that therefore Frieder Kempe's United Sates Patent no. 6,146,351, which teaches a method of reducing Delayed Onset Muscle Soreness inherently teaches treatment of pain resulting from inflammatory diseases.

3. In my opinion, it is incorrect to characterize Delayed Onset Muscle Soreness (DOMS) as an inflammatory disease. DOMS is a direct result of injury to muscle from micro-trauma secondary to overuse. This results in an inflammatory PROCESS not an inflammatory DISEASE. By contrast, an inflammatory disease is created by an autoimmune disorder or infective agent, not micro-trauma. In that sense DOMS is more similar to a sprained ankle, for example, than it is to a disease.

4. Due to the difference in the nature of DOMS as compared to a disease, a physician in my field would not refer to DOMS as an inflammatory disease. Nor would a physician in my field expect that a treatment for DOMS would also successfully treat inflammatory diseases such as gout, infective or rheumatoid arthritis.

5. I have no financial interest in this invention.

6. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

DB Clement

Dr. Douglas B. Clement

CURRICULUM VITAE

Douglas Bruce Clement CM BSc MD FACSM

1. CONTACT INFORMATION

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2. BIOGRAPHICAL DATA

Place of Birth: Montreal, Quebec Citizenship: Canadian
Social Insurance Number 706 773 066
Marital Status; Married Children: two

3. EDUCATION

Undergraduate: University of Oregon, Eugene, Oregon 1955 BSc
Graduate: University of British Columbia, Vancouver, BC MD 1959
Professional; Internship, St Mary's Hospital, San Francisco, California 1960

4. PROFESSIONAL EMPLOYMENT RECORD

1960 to 1979 Family Practice and Sports Medicine, Richmond, BC
1976 to 1979 Associate Professor (adjunct), Kinesiology, Simon Fraser University, Burnaby BC
1979 to 1985 Assistant Professor, Faculty of Medicine, University of British Columbia
1985 to 1990 Associate Professor, Faculty of Medicine, University of British Columbia
1990 to 1998 Professor, Faculty of Medicine, University of British Columbia

5. PROFESSIONAL ACTIVITY

Canadian Medical Association
British Columbia Medical Association, Past Board of Directors
Canadian Academy of Sports Medicine, Past President
Canadian Association of Sports Science, Past Secretary
American College of Sports Medicine

6. AWARDS AND DISTINCTIONS

Order of Canada
Canada- Centennial Medal
Canada- Canada 125 Medal
Canada- Golden Jubilee Medal

Canada-Lifestyle Medal
Canada- Vanier Award
Sports Medicine Council of Canada- Lifetime Achievement Award
Canadian Academy of Sports Medicine- R. Tait McKenzie Medallion
Canadian Academy of Sports Medicine- Honourary Lifetime Membership
Canadian Academy of Sports Medicine-Lance Richards Memorial Lecture
Coaching Association of Canada- Geoff Award for Lifetime Achievement
Canadian Olympic Committee- Hall of Fame
British Columbia Medical Association- Silver Medal Award for Service
British Columbia Sports Hall of Fame
Sport BC- Coach of the Year
Sport BC- Darryl Thompson Award
University of British Columbia-Faculty of Medicine, Distinguished Medical Lecturer
University of British Columbia-Wallace Wilson Award
University of British Columbia- Sports Hall of Fame

6. Sport Medicine Consultant

Athletics Canada 1981 to 1993
Canadian Olympic Committee 1976 to 1984
National Hockey League- Vancouver Canucks 1992 to 1999

Paper No.:___

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Inventor(s): Frieder K. Kempe
Title: **METHOD AND ARTICLE FOR THE TREATMENT OF INFLAMMATORY DISEASE**
Serial No.: 10/682,083
Filed: 10/10/2003
Examiner: Shumaya B. Ali Art Unit: 3743
Date: 18 January, 2007

To: Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia
22313-1450

DECLARATION UNDER 37 CFR 1.132

I, Dr. Cecil Hershler, of 4490 1st Ave W, Vancouver, British Columbia, Canada V6R 4J4, duly sworn, state:

1. I am a Medical Doctor and am currently the Director of the Vancouver Pulsed Signal Therapy Clinic, a position I have held since 1997. I have been in private medical practice since 1990. I am a specialist in the field of Physical Medicine and Rehabilitation and obtained my M.D. in 1980 from McMaster University and speciality qualifications in 1984 also from McMaster University. I have degrees in Physics and Electrical Engineering. I have served at the University of British Columbia as Clinical Associate Professor in the School of Rehabilitation Medicine and Director of the Residency Training Program, as well as Adjunct Professor in the Department of Mechanical Engineering.

2. I understand that the United States Patent Office Examiner in this application takes

the position that Delayed Onset Muscle Soreness (DOMS) is an inflammatory disease, and that therefore Frieder Kempe's United Sates Patent no. 6,146,351, which teaches a method of reducing Delayed Onset Muscle Soreness inherently teaches treatment of pain resulting from inflammatory diseases.

3. In my opinion, based on my medical experience, Delayed Onset Muscle Soreness (DOMS) is not an inflammatory disease. Inflammatory diseases are diseases characterized by inflammation (swelling, redness, heat) whereas DOMS is characterized simply by muscle soreness (tenderness).

4. Further in my opinion, based on my medical experience, it would not be expected that a treatment which reduces Delayed Onset Muscle Soreness (DOMS) would also successfully treat inflammatory diseases such as arthritis or tendinitis. DOMS is simply a disorder of pain in muscle.

Sworn before me at the City of)
Vancouver, British Columbia)
this 18th)
day of January, 2007)
)
)

Notary Public

BRUCE M. GREEN
Barrister & Solicitor
480 - 601 West Cordova St.
VANCOUVER, B.C. [illegible]

Cecil Hershler

Dr. Cecil Hershler

Related Proceedings Appendix

There are no related proceedings.